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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,114	06/16/2005	David Frederick Horrobin	P70482US0	8859

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,114	HORROBIN ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-14 are rejected under 35 USC 103(a) as being unpatentable over **WO/2000/044361** ('361) in view of **Casper, RC** ("Casper", "*Depression and Eating Disorders.*"; Depress Anxiety; 1998; 8 Suppl. 1:96-104.).

'361 discloses a pharmaceutical preparation comprising EPA in an appropriately assimilable form where of all the fatty acids present in the preparation at least 90%, and preferably at least 95%, is in the form of EPA and where less than 5%, and preferably less than 3% is in the form of DHA or any other fatty acid which may compete with EPA (page 3, lines 4-16) is provided for the treatment of a psychiatric or central nervous disorder. The preparation may be administered with conventional drugs to treat psychiatric or central nervous disorders to improve their efficacy or reduce their side effects (abstract; instant claims 1-3 and 6-8). The psychiatric disorder or nervous system disorder may be depression or anxiety (claims 8-9 and 23-24) and EPA may be in the form of ethyl EPA (claim 4; instant claims 4 and 5). '361 also teaches that EPA is preferably the ethyl derivative (claims 4; instant claims 4-5 and 9) and may be given at dosage of 1g/day (page 13, lines 16-20) or when supplied alone, the useful daily dose of EPA may be in the range of 0.05 g to 50 g/day, preferably 0.1 g to 10 g/day and very preferably 0.5 g to 5 g/day. (page 37, lines 7-9; instant claim 10) . The composition may be administered orally via delivery systems known to those skilled in the art; it may also be administered intravenously, intramuscularly, and by other parenteral routes (page 25, line 22 to page, line 6; instant claims 11 and 12). The reference does not expressly teach treating anorexia nervosa (AN).

Casper teaches in the abstract the prominence of depressive symptoms and depressive disorders in eating disorders such as anorexia and bulimia. On page 101 in the second paragraph, the secondary reference clearly accepts that, clinically, depressive disorder triggers anorexia nervosa.

At the time, it would have been obvious to one of ordinary skill in the art to use the composition as claimed to treat anorexia nervosa. The motivation would have been to make a composition with high amounts of EPA to treat those suffering from increased weight loss who are reluctant to orally ingest. The patient is much more likely to comply with the lower volumes required with the highly purified compound (see '361, page 12 line 18-20). Also the purer the preparation of EPA the more likely is it to occupy the relevant active binding sites, and the more likely is it to be able to have desirable biological effects.

Applicant has cited the secondary reference to argue that anorexia nervosa is not necessarily the same as anorexia. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection which is necessitated by amendment. Applicant, asserting that there are AN patients who are not depressed, further argues that the secondary reference draws a distinction between depressives and AN sufferers. The Examiner agrees that there is a distinction drawn between the 2 diseases but not to extent that would preclude expressive disorders from being related to AN. The distinction is in the etiologies of the 2 disease not the cause of one disease by the other. In fact, the reference, after drawing the distinction, clearly states that, clinically, depressive disorder can trigger anorexia nervosa. It is, therefore,

in arguendo, submitted by the Examiner that even if there are AN patients who are not depressed, there is clear overlap of AN and depression in patients since depression can sometimes lead to AN. Accordingly, one skilled in the art would understand that since EPA is useful in treating depression (as taught in the primary reference, then it can therefore, be use to treat a disease that depression sometimes leads to, such as AN.

Applicant has introduced 2 references (published later than the reference's filing date) as support that there is not a clear link between AN and depression. Applicant further stated on page 7 of the response filed 03/07/2008:

> "Even today, published papers fails to show a clear link between psychiatric disorders and eating disorders. We again refer the Examiner to the attached paper by Claudino A et al. (Treasure J. Cochrane Database Syst Rev. 2006 Jan 25;(1):CD004365) and in particular to the Author's conclusion on page 16 of the paper. Despite comparing a number of studies into the effect of various antidepressions on patients suffering from AN, **the authors could "not find evidence of efficacy of antidepressants in the acute phase of AN**". *Emphasis Added.*

The articles merely refer to certain authors' opinions. The secondary reference's author draws a different opinion. Absent any clear factual evidence, no probative value can be assigned to the teachings of these articles. Furthermore, the articles seem to be discussing a link with **acute** phase of AN. The claims do not require this limitation.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612